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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/016,634 | 10/31/2001 | Yongming Sun | DEX-0255 | 7580 |

26259 7590 12/02/2003

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| EXAMINER | |
|---|---|
| BORIN, MICHAEL L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/016,634 | SUN ET AL. | |
| | Examiner | Art Unit | |
| | Michael Borin | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6 and 10-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-5 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/20/2003* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☒ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Status of Claims*

1. Claims 1-17 are pending.

Response to restriction requirement filed 09/11/2003 is acknowledged. Applicant elected, with traverse, Group I, claims 1-5, 7-9 as drawn to polynucleotide SEQ ID No. 19 encoding polypeptide SEQ ID No. 115. Applicant argues that search of a polypeptide together with polynucleotide encoding the peptide would not be burdensome. First, polypeptides and polynucleotide are separately classified which would require separate searches of patent literature. Second, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately.

The restriction requirements still deemed proper and is therefore made FINAL. Claims 6, 10-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

The pending claims are addressed to the extent they read on the elected polynucleotide SEQ ID No. 19.[1]

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[1]With respect to polypeptide SEQ ID No. 115 mentioned in the election, there is no information in the specification on any polypeptide encoded by polynucleotide SEQ ID No. 19. Also, the examination addresses the addresses the elected polynucleotide species, rather than

Cancellation of claims 6, 10-17 , and amendment of claims 1-5,7-9 to read on elected species are requested.

***Priority***

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the elected SEQ ID NOs. No CRF was filed with the provisional applications to which priority is claimed. It is possible that the provisional application recites a sequence which is the same as instant SEQ ID NOs, but in the absence of a CRF for the application, the examiner has no way of determining whether any sequence recited in the provisional application is identical to instant SEQ ID Nos. Given the large number of sequences recited in the provisional application, and given the size of SEQ ID Nos. in the present case and each of the sequences recited in the provisional application, it would require undue effort on the part of the examiner to determine which, if any, of the sequences recited in the provisional application is identical to instant SEQ ID Nos. Prior art published after the parent applications but before the filing date of the instant application may have been

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polypeptide species. Consequently the genus of polynucleotides encoding polypeptide SEQ ID No. 115 is not being examined.

cited in this Office action. If they wish to contest the citation of the intervening prior art, applicants are requested to provide clear evidence that the elected inventions are disclosed in the parent application.

Applicant is requested to point to the specific SEQ ID number(s) in any or each of the provisional applications that correspond to the elected SEQ ID NOs, and to the specific page and line, or to the specific page and Table designation where the corresponding SEQ ID NOs. are taught. In the absence of any indication of such correspondence and/or an alignment showing identity between SEQ ID NOs, priority is not granted to the provisional application, and the instant application is granted priority only to its filing date.

***Claim Objections***

3. Claims 4-10 are objected because they do not reflect the elected subject matter. Applicant elected polynucleotide SEQ ID No. 19 encoding polypeptide SEQ ID No. 115. The claims do not reflect the elected subject matter. Amendment of the claims to read on the polynucleotide of SEQ ID 808 is requested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The invention is drawn to genomic DNA or cDNA or RNA specific to colon cells or colon tissue (see p. 6). The exact sequence SEQ ID No. 19 meets the provision of written description. However, the claims encompass gene sequences, encoding sequences and so forth. None of these products meet the written description provision of 35 USC 112, first paragraph as there is no description of other elements included in DNA, such as non-coding, regulatory regions, etc. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date

sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of nucleic acids consisting of sequences of identified SEQ ID Nos, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Therefore, only nucleic acid consisting the identified SEQ ID No 19, but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

5. Claims 1-5,7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn, in part, to polynucleotides having at least 75% sequence identity with SEQ ID NO: 19. The specification discloses SEQ ID NO:19 as specific to colon cancer or cancer tissues. Polynucleotide SEQ ID No. 19 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims drawn to nucleotide sequences having more than 75% identity to the elected SEQ ID 19, do not have sufficient description in the specification as description of

species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less then 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. Therefore, sequence similarity result in an unpredictable and therefore unreliable correspondence between the newly discovered sequence and a similar biomolecule of known function or expression. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be specific to colon cancer cells is present in the specification. With the exception of SEQ ID NO: 19, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. The species specifically disclosed are not representative of the genus because the genus is highly variant. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. Accordingly, the specification does not provide a written description of the

invention of claim 1, and, consequently, of its expression cell and vector of claims 7-9, as well as polynucleotides hybridizable to such polynucleotide. Therefore, only SEQ ID NO: 19 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph.

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claimed SEQ ID No. 19 is genomic DNA revealed by screening genomic DNA database. Applicant is not in possession of a cDNA comprising SEQ ID No. 19.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> /b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

7. Claims 1,3-5 are rejected under 35 U.S.C. 102(f). The claims are drawn to polynucleotide SEQ ID NO: 19. As admitted in the applicant's disclosure (specification, p. 116, lines 18-20), in detecting overexpression of said polynucleotide applicants screened proprietary genomic database LIFESEQ Gold commercially available at that time from Incyte Genomics Inc. (see, e.g., press release "Incyte and Vertex Enter Genomic Partnership to Accelerate Drug Discovery in Multi-target Gene Families Using LifeSeq Gold, February 29, 2000", http://www.vpharm.com/Pressreleases2000/pr022900.html). Consequently, applicants did not themselves invent the claimed subject matter.

8. Claims 1,3-5 are rejected under 35 U.S.C. 102(a) as being anticipated by genomic database LIFESEQ Gold (see reference in the preceding paragraph). According to applicant's admission (specification, p. 116, lines 18-20),the information about the claimed subject matter was present in said database prior to the invention.

9. Claims 1,2, 4,5,7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by GenEMBL Accession Number AK 026675 which describes a human cDNA which

has 98% local similarity to instant SEQ ID No. 19 (see sequence alignment). As the referenced sequence has continuous stretches matching the claimed sequence of SEQ ID No. 19 (see attached sequence alignment) it would be expected to hybridize to SEQ ID No. 19.

***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-5, 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 1 is vague and indefinite because it claims more than was elected.

B. The recitation of "selectively hybridize" (claim 1) is vague, indefinite and incomplete because the term is a relative one and no frame of reference is given. The determination of characterization of selective hybridization requires knowledge or

disclosure of other hybridization targets and/or probes in the reaction mixture. None is given or mentioned; thus the claim is vague, indefinite and incomplete.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014. Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

November 21, 2003

mlb